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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, Division of Eli Lilly & Co. The supplemental NADA provides for use of monensin Type A medicated articles to make Type B and C medicated cattle feeds to be fed at 0.14 to 0.42 milligram per pound (mg/lb) of body weight per day, to revise feeding directions, to provide added uses for monensin Type C medicated feeds for prevention and control of coccidiosis, and to amend the residue tolerances for monensin residues.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-7575.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly& Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95–735 that provides for using Rumensin® (20, 30,45,60, 80, and 90.7 grams per pound (g/lb) monensin sodium) Type A medicated articles to make monensin Type B and C medicated cattle feeds. The monensin Type B and C medicated feeds are fed to cattle at 0.14 to 0.42 mg/lb of body weight per day, for feedlot cattle at a maximum of 360 mg/head/day for prevention and control of coccidiosis, for pasture cattle at 50 to 200 mg/head/day for increased rate of weight gain, for mature reproducing

beef cattle at 50 to 200 mg/head/day for improved feed efficiency, and for nonveal calves at 50 to 200 mg/head/day for prevention and control of coccidiosis. The supplemental NADA is approved as of December 16, 1998, and the regulations are amended in 21 CFR 558.355 (d)(7) (ii), (f)(3) (iii), (f)(3) (vi), and (f)(3)(vii), and by adding (f)(3) (xi), to reflect the approval.

In addition, an acceptable daily intake (ADI) for residues of monensin in edible tissues of cattle has not been previously established, therefore, 21 CFR 556.420 is amended to provide an ADI for monensin residues.

In accordance with the freedom of information provisions of21 CFR part 20 and 514.11 (e)(2) (ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under 21 U.S.C. 360b(c)(2)(F)(iii), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning December 16, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, for food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use for prevention and control of coccidiosis in pasture cattle, mature reproducing beef cows, and nonveal calves.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 *CFR Part 556*

Animal drugs, Foods.

21 *CFR Part 558*

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. **342, 360b, 371.**

2. Section 556.420 is revised to read as follows:

§ *556.420* Monensin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of monensin is 12.5 micrograms per kilogram of body weight per day.

(b) *Tolerances—(l) Cattle and goats.* A tolerance of 0.05 part per million is established for negligible residues of monensin in edible tissues of cattle and goats.

(2) *Chickens, turkeys, and quail.* A tolerance for residues of monensin in chickens, turkeys, and quail is not needed.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. **360b, 371.**

4. Section 558.355 is amended by revising paragraphs (d)(7)(ii), (f)(3)(iii)(*a*) and (f)(3)(iii)(*b*), (f)(3)(vi)(*a*) and (a), (f)(3)(vii)(*a*) and (f)(3)(vii)(*b*), and by adding paragraph (f)(3)(xi) to read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(7) * * *

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle.

* * * * *

(f) * * *

(3) * * *

(iii) * * *

(*a*) *Indications for use.* For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

(b) Limitations. Feed to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1 pound of feed or, after the 5th day, feed at a rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed.

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(vi) * * *

(*a*) *Indications for use.* For improved feed efficiency; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(b) Limitations. Feed to mature reproducing beef cows. Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency,

feed continuously at a rate of *50* to *200* milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day.

(vii) * * *

(*a*) *Indications for use.* For improved feed efficiency; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(b) Limitations. For feedlot cattle, feed continuously to provide 50 to 360 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 360 milligrams per head per day.

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(xi) *Amount per ton.* Monensin, 10 to 200 grams.

(a) Indications for use. For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(*b*) *Limitations.* For calves excluding veal calves. Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day.

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Dated: 1/13/99

January 13, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Andrew J. Beaulieu
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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